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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,549

03/01/2004

Eugene R. Hickey

9/278

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06/04/2007

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EXAMINER

COPPINS, JANET L

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/790,549	Applicant(s) HICKEY ET AL.	
	Examiner Janet L. Coppins	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 in part is/are rejected.
- 7) ☒ Claim(s) 1-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-10 are pending in the instant application.

#### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statement (IDS), submitted April 12, 2004, has been considered by the Examiner. Please refer to the signed copy of Applicants' PTO-1449 form, attached to the instant Office Action.

#### ***Election/Restrictions***

3. Applicant's election without traverse of Group I, claims 1-9 in part, drawn to compounds of formula (I) or (II) wherein X contains morpholine, in the reply filed on May 10, 2007, is acknowledged. Claims 1-9 in part, wherein X contains other than morpholine, and claim 10 drawn to methods, withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

#### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-9 in part rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,420,364 B1 to Emmanuel et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicants are claiming piperidine carboxylic acid compounds according to formula (I) or (II) of claim 1, that are reversible inhibitors of cysteine proteases (namely cathepsin S), useful for treating autoimmune diseases, for example.

Emmanuel et al teach and recite piperidine compounds having the same core structure, please refer to compounds according to formula (I) of claim 1. The compounds claimed in the '364 patent fully encompass the compounds of the instant invention and are also useful for inhibiting cysteine proteases for treating autoimmune diseases.

The only difference between the prior art and the claims is that the '364 patent does not teach a single disclosed compound or species that anticipates the instant claims.

However, minus a showing of unobvious results, it would have been obvious to one of skill in the art to prepare the piperidine compounds as instantly claimed since the prior art reference discloses a similar genus of compounds with the same activity of inhibiting cysteine proteases. The '364 patent teaches a larger genus of compounds that completely encompass the smaller genres that are instantly claimed as formulae I and II of claim 1. One would be motivated to prepare the instantly claimed invention since Emmanuel et al has enabled and taught the broad scope of compounds in the many examples disclosed and claimed in the '364 patent. The Examiner directs Applicant's attention to formula I, defined in claim 1, wherein "Het" is piperidinyl; X is O; Y is O; R<sub>1</sub> is morphonlinyl; R<sub>2</sub> is hydrogen and R<sub>3</sub> is alkyl that is

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further substituted by alkyl; R<sub>4</sub> is hydrogen at both occurrences, please refer to RN 331278-80-9, RN 331278-81-0, RN 331278-82-1, RN 331278-83-2, RN 331278-90-1, RN 331279-08-4, and RN 331279-09-5, for example.

### ***Claim Objections***

6. Claims 1-9 objected to for containing non-elected subject matter (i.e. compounds not containing a morpholine ring within the "X" substituent).

### ***Conclusion***

7. In conclusion, claims 1-10 are pending, claims 1-9, in part, and 10 are currently withdrawn from consideration, and claims 1-9 stand rejected.

### ***Telephone Inquiry***

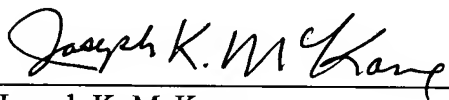
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins  
May 28, 2007

  
\_\_\_\_\_  
Joseph K. McKane  
SPE, Art Unit 1626